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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,502	07/13/2001	Victor Rubio Susan	4512/00012	8777

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,502	Applicant(s) RUBIO SUSAN ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-35 is/are pending in the application.
- 4a) Of the above claim(s) 26-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-25 and 34-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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The application should be reviewed for errors and conformity with domestic practice. For example, standard U.S. spelling should be used.

The amendment filed 10/29/03 is acknowledged. Claims 11-25 and 34-35 are being considered on the merits.

Claims 26-33 are withdrawn from consideration as directed to a non-elected invention.

Newly submitted claims 26-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 11-25 and 34-35 are drawn to a process of protecting a plant from pathogenic fungi using certain binucleate *Rhizoctonia*.

Claims 26-33 are drawn to a process of selecting a sample of binucleate *Rhizoctonia* by determining if it has a certain nucleotide sequence.

Each of groups I and II is directed a separate and distinct invention. The method of group I is directed to a process of protecting a plant from pathogenic fungi by allowing a strain to grow with a plant, while the process of group II is a selection process which involves molecular screening tests to determine whether a strain does or does not have a certain sequence. These methods have different steps and different purposes.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The amendment filed 10/29/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the

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original disclosure is as follows: The material at page 4 starting at line 27 and the material at page 14, line 15.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's assertions that the skilled person would recognize that the sequences according to SEQ ID NOS. 1 to 14 were target sequences from the isolates themselves and not primers directed thereto and that they are within SEQ ID NOS 15 to 25 is noted. However no alignment or other evidence is provided to substantiate these contentions. The sequences are not short enough to make the alleged relationship readily apparent. Moreover, applicants averred in the oath that the specification had been reviewed.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-25 and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite in that neither the amount of the strain nor the viability of the strain is claim designated. Language such as "viable" and "in an amount effective to protect a plant from pathogenic fungi" would be remedial.

Claims 19 and 20 are confusing in that the distinction between inoculating and allowing to be colonized is unclear. Alternatively, it is unclear how colonization with a particular strain is "allowed" in the absence of inoculation.

Claim 34 is vague indefinite and confusing in the provision of a plant, seed or seedling "associated with" certain binucleate *Rhizoctonia*. It is unclear how this would protect another plant seed or seedling.

Claim 35 is incomplete and confusing in that it is unclear whether a tiny fragment of "a mycelium" of a given binucleate *Rhizoctonia* would be protective for plants when provided in traces and no matter how dilute. It is also apparent that the strain has to be viable to be protective.

Claims 24 and 25 are vague and indefinite in the recitation "wherein providing includes selling", inasmuch as it is unclear how the further step(s) are to be carried out to complete the "protecting" aspect of the invention as claimed.

Claims 11-25 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to protection of plants with strains characterized as having an ITS1 DNA which has 90% homology to SEQ ID NO:20. In contrast, the specification only provides guidance regarding the use of strains having a specific sequence, in this instance, SEQ ID NO 20 (Specification page 5, paragraph 4). No guidance is presented for the alteration of any part of any recited sequences or of SEQ ID NO:20, specifically. No guidance is presented regarding the evaluation of strains selected at random for the required homology to SEQ ID NO:20 or regarding which part of that sequence is required to result in effective protection of plants with the strain. Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA

sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Moreover, there is no clear indication on this record that strains having the required homology and which are suitable for plant protection are freely available to the public. Applicant appears to have deposited certain strains under Budapest Treaty (Specification pages 5-6). However, the record does not clarify which strain(s) are encompassed by the invention as claimed. Once suitable strains are identified, for compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicants now indicate that the ITS1 gene is taught at Fig 1, line 6 and related to the Eab F1 isolate of the species *Ceratobasidium albasitensis*. It is unclear what the phrase "this taxon is part of the *Rhizoctonia* s.l. species complex and genus *Ceratobasidium* is intended to mean. A taxon is a group or category, at any level, in a system for classifying plants or animals. The genus *Ceratibasidium* and the genus *Rhizoctonia* are in different groups or categories, i.e., in different taxa. Moreover, the arguments regarding the designation now argued is based on an article by the inventors dated 2002 paper, while the application was filed in 2001. A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date. In re Glass, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974). See also, MPEP 608.01(p) regarding the completeness requirement at the time of filing.

Claims 11-12, 18, 19-23, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Herr (1988) or Cardoso *et al.* (1987).

The claims are directed to the protection of plants from fungi by using biocontrol with binucleate *Rhizoctonia* having an ITS1 sequence which is at least 90% homologous with SEQ ID NO. 20.

Herr and Cardoso *et al.* each discloses processes of the protection of plants from fungi by using biocontrol with binucleate *Rhizoctonia*. (See, e.g., Table 5; Tables 2 and 3). Even though the reference is silent as to whether or not the strains used have the required sequence, the binucleate *Rhizoctonia* are effective in the protection of plants from fungi as claimed. Thus, it can reasonably be presumed that the strains inherently possess the required sequence.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to the argument that the references fail to associate protective ability with a specific strain is irrelevant to the claimed invention. The possession of a certain sequence is an inherent property and is not dependent on identification thereof. Contrary to applicant's contentions, there is no clear correlation between strains having at least 90% homology to a sequence of SEQ ID NO. 20 and protective properties of biocontrol against fungi.

Therefore the rejection is deemed proper and it is adhered to.

Claims 11-25 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herr taken with Cardoso. The claims are directed to the protection of plants from fungi by using biocontrol with binucleate *Rhizoctonia* selected by molecular detection of the ITS ribosomal sequence.

As noted supra, Herr and Cardoso *et al.* each discloses the protection of plants from fungi by using biocontrol with binucleate *Rhizoctonia*. (See, e.g., Table 5; Tables 2 and 3). Even though the reference is silent as to whether or not the strains used have the required sequence, the binucleate *Rhizoctonia* are effective in the protection of plants from fungi as claimed. Thus, it can reasonably be presumed that the strains possess the required sequence. There is no clear correlation between strains having at least 90% homology to a sequence of SEQ ID NO. 20 and protective properties of biocontrol against fungi.

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The references differ from the claimed invention in the types of plants to be treated and in that the sale of a binucleate *Rhizoctonia* is not disclosed. However, one of ordinary skill in this art would have a reasonable expectation of success in treating pathogenic fungi on various plants by applying the methods and strains disclosed by Herr and Cardoso *et al.* with respect to sugar beet. In addition, the source of the strain to be used, whether it is obtained by purchase/sale, as a gift or by *de novo* isolation does not affect the outcome of protection of plants from pathogenic fungi.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of protection of Herr or Cardoso *et al.* by using the strains taught by the references to protect further plants from pathogenic fungi and provide such strains to farmers, for example, by selling them, for the expected benefit of providing strains of binucleate *Rhizoctonia* identified to be suitable for biocontrol of fungi on plants and thus increase the yield of important agricultural crops..

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's arguments regarding the Gonzales reference are not relevant to the references applied, since each of Herr or Cardoso *et al.* have identified strains that are suitable for biocontrol of fungi. The claims are not directed to a method of identification of such fungi as appears to be argued, but rather to a method of protecting plants. These methods are taught by Herr and Cardoso *et al.*. Applicant has not demonstrated with objective evidence that the strains provided by Herr or Cardoso *et al.* fail to possess at least 90% homology to a sequence of SEQ ID NO. 20.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

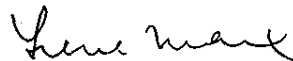
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx
Primary Examiner
Art Unit 1651